

### **REMARKS**

This Amendment, filed in reply to the Office Action dated December 22, 2008, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 11-14, 25-27, 30-33, 35 and 37 are rejected. Claims 11, 13, 30 and 37 are amended herewith. Claim 12 is canceled herewith without prejudice or disclaimer. Claims 11 and 37 are amended herewith to incorporate the subject matter of Claim 12. Further support for the amendments to Claims 11 and 37 can be found throughout the specification as originally filed, and at, for example, page 4, line 22. Claim 13 is amended herewith to correct antecedent basis in view of the cancellation of Claim 12. The amendment to Claim 30 is solely to improve clarity.

No new matter is added by way of this amendment. Entry and consideration of this Amendment are respectfully requested.

### **Drawings**

Applicants thank the Examiner for acknowledging acceptance of the Drawings submitted October 19, 2004.

### **Claim to Priority**

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority, and for acknowledging receipt of a certified copy of the foreign priority document, namely GB 0209007.4.

### **Objections to the Specification**

On page 2 of the Office Action, the specification is objected to as allegedly lacking a sufficiently descriptive title.

Applicants respectfully submit that the amended title submitted herewith overcomes the objection.

Withdrawal of the objection is respectfully requested.

### **Objections to the Claims**

On page 2 of the Office Action, Claim 30 is objected to under 37 CFR 1.75(c), as allegedly being of improper dependent form.

Specifically, the Examiner contends that Claim 30 fails to further limit the subject matter of Claim 11 or Claim 37, from which it depends.

Initially, Applicants strongly disagree that Claim 30 improperly depends from Claim 11. Specifically, Applicants note that Claim 30 recites that the “sterilized nutrient composition is a *dried* autolysate of a bacterial biomass.” (Emphasis added.) Claim 11, however, recites that the sterilized nutrient composition is prepared by autolysis of bacterial cells, and “optionally followed by ultrafiltration and evaporation.” (Emphasis added.) Claim 11 neither recites nor requires that the sterilized nutrient composition be dried, as is recited in Claim 30. Accordingly, Claim 30 is further limiting of, and is properly dependent from, Claim 11.

Further, in the interest advancing prosecution of the Application, Applicants herewith amend Claim 30 to depend solely from Claim 11. Applicants respectfully submit that the amendment overcomes the objection.

Withdrawal of the objection is respectfully requested.

### Withdrawn Rejections

1. Applicants thank the Examiner for withdrawal of the rejection of Claims 28 and 29 under 35 U.S.C. § 112, first paragraph, as set forth in the prior Office Action.
2. Applicants thank the Examiner for withdrawal of the provisional nonstatutory obviousness-type double patenting rejection over copending Application No. 10/504,464.

### Claims 11, 13, 14, 25-27, 30-33, 35 and 37 are Patentable Under 35 U.S.C. § 103(a)

On page 3 of the Office Action, Claims 11-14, 25-27, 30-33, 35 and 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bothe *et al.*, Norferm, DA, Larsen & Joergensen, Atlas & Parks and Patz *et al.*, essentially for reasons of record.

In response to Applicants' previous argument that the claimed composition possesses an unexpected and unobvious property, *i.e.*, that it allows unexpectedly superior growth of a broad spectrum of different bacteria, such as gram-positive, gram-negative, aerobic and anaerobic bacteria, the Examiner asserts that such arguments are not persuasive for the following reasons.

First, on page 10 of the Office Action, the Examiner states that "Applicants' argument that the growth substrate disclosed in the prior art is not suitable as a "broad-spectrum" growth substrate for microorganisms, is not found to be persuasive because [the] claims [as] presented do not specifically require such limitations." That is, it appears as though the Examiner suggests that the unexpected results asserted by Applicants *must* be claimed, even though neither the statute nor relevant law require as such.

Second, on the same page, the Examiner also appears to indicate that Applicants have not demonstrated that the closest prior art applied in the rejection, *i.e.*, Patz *et al.*, does not possess the unexpected result claimed by Applicants.

Third, the Examiner appears to suggest that Applicants' showing of unexpected results is not sufficient to overcome the rejection because the claims currently under examination are directed to a product, and not a process. Specifically, on page 11 of the Office Action, the Examiner emphasizes that "it is noted that the invention as claimed is directed to a product." Further, on the same page, the Examiner states that "[A]pplicants arguments regarding "superior growth" and "specifically" suitable for growing a particular species of bacteria, is not found to be persuasive because [the] instant claims are not directed to a method or process of culturing or growing certain microorganisms using such composition as claimed."

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

As an initial matter, with regard to the Examiner's assertion that Applicants averment of unexpected results is not persuasive because Applicants have not provided a comparison against the product of Patz *et al.* (which is asserted in the rejection to be the closest prior art), Applicants note that such refers to evidence not required by statute or law. Rebuttal of an obviousness rejection by a showing of unexpected properties may take the form of a comparison to the closest prior art, to subject matter more closely related to the claimed invention than the closest prior art, or by demonstration of a substantial degree of unpredictability in the pertinent art area. See, for example, *In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978) and *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978).

Applicants note that the specification as filed provides a demonstration of unexpected properties through a comparison of the claimed invention vis-à-vis subject matter *more closely related* to the claimed invention than that applied in the rejection. Specifically, Applicants provide experimental data comparing growth substrates prepared with a biomass produced by

autolysis of *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525), which is termed "BP Autolysate," and with a biomass produced by subjecting the "BP Autolysate" to ultrafiltration and evaporation, which is termed "BP Extract," to growth substrates recognized in the art as being specifically suitable for growing the particular species of bacteria tested. See Table 1 and Example 2 of the specification as filed. Moreover, in Example 2, Applicants provide a comparison of BP Autolysate and BP Extract vis-à-vis BP homogenizate and BP Permeate, the latter two growth substrates representing closer embodiments than that of Putz *et al.* because, rather than employing a *single* bacterial species (*i.e.*, *Methylbacterium rhodesianum* IMET 11401), the BP homogenizate and BP permeate contain all the bacterial species recited in the instant claims. As shown in Table 1, the claimed growth substrates (*i.e.*, BP Extract (Claims 11 and 37) and BP Autolysate (Claim 11)) exhibit unexpectedly superior growth of a broad-spectrum of bacteria, spanning gram-positive, gram-negative bacteria, aerobic and anaerobic bacteria, vis-à-vis either the control substrates, or the growth substrates prepared with BP homogenizate or BP permeate. This same data also demonstrates substantial unpredictability in the pertinent art area, *i.e.*, as to which biomass processing steps result in a biomass imparting the unexpectedly superior broad-spectrum growth characteristics to a growth substrate. As discussed above, such unpredictability is also relevant to rebuttal of an obviousness rejection by a showing of unexpected results.

To further support Applicants' averment of unexpected results, Applicants attach herewith a Rule 132 Declaration by Dr. Gunnar Kleppe, previously Chief Scientific Officer of Norferm DA, which provides the raw data used to compile Table 1 in the specification as filed. An executed copy of the Declaration, in color, will follow. The Declaration explains the

unexpected properties and the practical significance thereof of growth substrates produced with a biomass produced by autolysis of *Methylococcus capsulatus* (Bath) (strain NCIMB 41526), *Ralstonia* sp. DB3 (strain NCIMB 41527), *Aneurinibacillus* sp. DB4 (strain NCIMB 41528) and *Brevibacillus agri* DB5 (strain NCIMB 41525), *i.e.*, “BP Autolysate,” and with a biomass produced by subjecting the “BP Autolysate” to ultrafiltration and evaporation, *i.e.*, “BP Extract.” The data in Tables A and B on page 4 of the Rule 132 Declaration represent the raw data used to compile Table 1 in the specification as filed.

As noted in the Declaration, the growth substrates employed in the experiments depicted in Tables A and B were produced by the method set forth in Example 1 in the specification as filed, *i.e.*, the relevant biomass (*e.g.*, BP Autolysate, BP Extract, etc.) was added to either glucose, or glucose and NMS (nitrate mineral salts; designated as “salts” in Table A). Thus, Table A demonstrates that growth substrates prepared by adding BP Extract or BP Autolysate to demineralized water, with the addition of glucose, produces a broad-spectrum growth substrate that, depending on the specific bacteria tested, is either equivalent, or markedly superior, in terms of bacterial growth *vis-à-vis* art-recognized growth media specially selected for growth of that particular bacterial species. See page 5, first paragraph, of the Rule 132 Declaration, and the attached Annexes. One of ordinary skill in the art could not have expected or predicted such remarkable suitability as a broad-spectrum growth medium. In addition, as discussed on page 6 of the Rule 132 Declaration, Examples 6-8 of the specification as filed also demonstrates that the claimed growth substrates demonstrate unexpectedly increased viability and productivity (such as enzyme production and secondary metabolite production).

Further, in an effort to compact prosecution of the Application, Applicants herewith amend Claims 11 and 37 to further define the claimed carbon source as glucose, consistent with

the growth substrates employed in the experiments depicted in Tables A and B of the Rule 132 Declaration. Applicants respectfully submit that the unexpected properties are commensurate with the scope of the present claims, because Applicants have demonstrated that compositions containing just BP Extract (or BP Autolysate) and glucose possess this unexpected property. One of ordinary skill in the art would readily appreciate that the unexpected properties lie in the presence of BP Extract, or BP Autolysate, and glucose, and that the amounts thereof could be adjusted or optimized whilst maintaining the superior broad-spectrum growth capabilities of the medium. As such, those skilled in the art could reasonably extend the probative value of the Declaration evidence to the full scope of the present claims.

At least in view of the unexpected properties disclosed in the specification and in the Rule 132 Declaration attached herewith, Applicants respectfully submit that the present claims are patentable over the cited references. Clearly, such superior growth properties could not have been expected by one of ordinary skill in the pertinent art, and as such, would not have been obvious. Further, as discussed in paragraphs 5, 6 and 21 of the Rule 132 Declaration, these unexpected properties are of clear practical significance.

Further, Applicants respectfully submit that, from a legal standpoint, the Examiner's position that the unexpected results are only relevant to the patentability of claims directed to a process, and not the presently claimed product, is improper. For example, relevant law holds that a demonstration of a single unexpected use, or unexpected property, may impart patentability to claims directed to a *product*, as follows.

For example, in *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007), the Court held that an unexpected use was sufficient to impart patentability to claims to a *product*, stating that "[the Applicants had argued extensively that the] claimed composition exhibits the unexpected

property of neutralizing the lethality of rattlesnake venom while reducing the occurrence of adverse immune reactions in humans. Such a use and unexpected property cannot be ignored . . . [t]here is no basis in law for ignoring any property in making such a comparison. The issue here is not whether a claim recites a new use, but whether the subject matter of the claim possesses an unexpected use. That unexpected property is relevant, and thus the declarations describing it should have been considered by the Board." (Emphasis added.)

In *In re Schechter*, 205 F.2d 185, 40 (CCPA 1953), the court reversed the obviousness rejection of a claim to a group of cyclopentane *compounds*, on the ground that an unexpected biological function of the claimed compounds imparted novelty over a structurally similar prior art isomer.

Also, in *In re Lambooy*, 300 F.2d 950, 49 (CCPA 1985), the court reversed the obviousness rejection of a claim to an isalloxazine *compound* based on an unexpected result that the compound behaved as an anti-metabolite *in vivo*. Specifically, although the court acknowledged structural similarity with a prior art compound (which was a metabolite *in vivo*), the court stated that "in view of the biochemical differences [between the claimed compounds and the prior art compounds], we can only assume the solicitor is urging that while differences in chemical properties might be persuasive of patentability of the claimed compound, differences in biochemical properties are not to be considered. We see no reason to distinguish between chemical and biochemical properties and no reason or authority for this position has been presented."

Of particular note is *In re Papesch*, 315 F.2d 381 (CCPA 1963), in which the Examiner, in an analogous manner to the instant case, stated that the unexpected properties of the claimed compound, *i.e.*, unexpected anti-inflammatory activity, "are irrelevant to the rejection since it is



not directed to the subject matter sought to be patented [*i.e.*, product claims]. It appears that if an invention is present, it resides in the use of the claimed compounds as anti-inflammatory agents and should be claimed as such.” The Examiner in *Papesch* further opined that “[a]n unexpected difference in a single property should not be adequate to support a claim for a novel, but obvious, homologue, which claim will dominate all properties and uses of the homologue, including those differing only in the expected manner from the known product.” On appeal, the board did not disagree with the Examiner. The court however, reversing the Board’s decision, disagreed that the unexpected properties of the compounds were not relevant to the patentability of the compounds themselves. The court stated that “it will be seen that this and other courts, both before and after the enactment of section 103, have determined [the] obviousness and patentability of new chemical compounds by taking into consideration their biological or pharmacological properties ... [A]s to the examiner’s view that in a case such as this the applicant should claim his invention as a process utilizing the newly discovered property, the board appears to have ignored it, properly we think. It is contrary to practically all of the above decisions wherein no fault was found with granting product claims. Such claims have well-recognized advantages to those in the business of making and selling compounds, in contrast to process-of-use claims, because competitors in the sale of compounds are not generally users.” (Emphasis added.) The court dismissed the board’s opinion and decision as “**contrary to well established law.**”

The above decisions establish that even a single unexpected use or property of a product or composition may be sufficient to impart patentability to *product* claims, and that such an unexpected result or property need not be restricted to determining patentability of method claims. Accordingly, Applicants respectfully submit that, in view of the above-decisions, the

unexpected properties possessed by Applicants' claimed product are highly relevant to (and indeed sufficient to rebut) the outstanding obviousness rejection of product claims.

Withdrawal of the rejection is respectfully requested.

#### **Double Patenting**

On page 12 of the Office Action, Claims 11-14, 25-27, 30-33, 35, and 37 are *provisionally* rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 8, 13-25 and 27 of copending Application No. 10/504,463.

As this rejection is merely provisional in nature, Applicants respectfully request that the rejection be held in abeyance until such time as allowable subject matter is identified.

**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

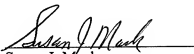
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**23373**

CUSTOMER NUMBER

Date: June 22, 2009

  
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